

IDENTIFICATION AND ACCOUNTABILITY SYSTEM FOR SURGICAL SPONGES

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*This application is a provision of Ser. No. 08/125,169.*Background of the Invention

1. Field of the Invention

The present invention relates to an identification and accountability system for surgical sponges and more particularly to an identification and accountability system for surgical sponges, which utilizes machine-readable information to identify and account for surgical sponges.

2. Description of the Related Art

Surgical sponges are commonly used during surgical procedures to absorb body fluids, mostly blood, of the patient both inside the incision and around the site of surgery. Sponges of this nature are usually made of an open ended absorbic fabric, such as woven cotton. When used, surgical sponges become saturated with blood, alter in size and shape and therefore become hard to distinguish from body tissue and each other. For this reason surgical sponges are hard to identify and account for both during and after a surgical procedure. This problem becomes magnified in larger surgical procedures where there are a large number of sponges used.

Before any particular surgical procedure all surgical items must be meticulously counted.

After the procedure all items used in that particular surgery must be identified and accounted for. Surgical sponges are a difficult item to account for before, during and especially after a surgical procedure. The current method of identification and accountability relies on medical personnel to count these items by hand, relying on human visual detection and counting ability to differentiate one sponge from another and account for all the sponges, leaving this method open to a degree of human error. If a sponge count taken during or after a surgical procedure does not match a sponge count taken during or after the same procedure, the sponges are impregnated with an x-ray detectable element so that the patient can be x-rayed to see if the missing sponge or sponges are inside the patient and where.

The current system of accountability and identification for surgical sponges has proven itself unreliable and inefficient. Not only does the large amount of time involved to differentiate the sponges from one another and account for them all lead to large costs, but also the unreliable nature of the method leads to an alarming number of miscounted sponges resulting in retained
5 surgical sponges inside the patient. These unfortunate incidents adversely affect not only the health of the patient, but also prove costly to the nurses, technicians, doctors, hospitals and insurance companies involved.

Past attempts have been made to increase the chances of accurate visual counting of surgical sponges. U.S. Patent No. 4,917,694 addressed this problem by including, in the sponge,
10 an elongated visually detectable element at a visible location on the sponge comprising a pair of elongated twisted strands. One of the strands contrasts with the color of the sponge, and the other with the color of blood. This is done to facilitate visual detection of the sponge whether it is dry or soaked with blood. This is done to facilitate visual detection of the sponge and counting ability and is therefore subject to a high degree of human error. There is no attempt to differentiate one
15 individual sponge from another.

U.S. Patent No. 4,114,601 attempts to solve the problem of medical item detection. It describes a method by which surgical implants, instruments, sponges, implantable devices and indwelling therapeutic devices and materials may be detected within the human body, or other area of interest, by incorporating or adding a radio frequency transponder. Non-linear mixing of two
20 frequencies in a radio transponder is used. This transponder may be a small film deposition of ferrite material exhibiting gyro-magnetic resonance at selected frequencies or a solid state device. When the transponders are incorporated in the items, the detection of the transponder is equivalent to the detection of the implant.

U.S. Patent No. 5,031,642 also attempts to address the issue of medical item
25 accountability. The invention is an "Integrator Collector" containing a time-correlated digital receiver for measuring, displaying and recording fluid loss from surgery and for maintaining, displaying and recording a count of secured items, such as needles and sponges by means of an electronic beam, which upon activation by a surgical sponge, triggers the automatic conversion of the weight of the items into cubic centimeters of blood loss.

30 The '642 patent calls for the placement of indicia on external packaging of the containers holding the surgical sponges as a means to count the number of sponges before a surgical

procedure, but makes no attempt to include this indicia on the individual sponges themselves. No attempt is made to differentiate one individual sponge from the next by means of indicia.

Objects and Summary of the Invention

5 It is therefore a principal object of the present invention to account for and identify surgical sponges in an efficient, reliable manner.

It is another object to provide an identification and accountability system for surgical sponges which is not obscured by the conditions that the system will be exposed to in its use, particularly exposure to body fluids including but not limited to blood.

10 It is another object to provide an identification and accountability system for surgical sponges which does not compromise any medical requirements thereof, particularly but not limited to requirements of sterility.

It is another object to provide this identification and accountability system in a way as not to compromise the function of the surgical sponges.

15 These and other objects are achieved by the present invention that, in one broad aspect, comprises machine-readable information located on individual surgical sponges. The machine-readable information is unique to each individual surgical sponge, making each and every sponge automatically differentiable from the next for at least a given surgical procedure. Each surgical sponge further preferably includes an x-ray detectable element.

20 Means are provided for automatically reading the individually unique surgical sponges and creating an inventory of the surgical sponges to be used for a particular procedure. An automated check of the inventory of surgical sponges can be obtained at any desired time before, during or after a surgical procedure.

The present invention provides for the improved identification and accountability of surgical
25 sponges by the incorporation of automatic identification technology to these sponges in a manner that allows for the differentiation of the individual sponges from each other. This is done through the impregnation of unique machine-readable information to each individual sponge that is unique for at least a surgical procedure. By the incorporation of automatic identification and recognition technology described herein, the human error factor which so negatively affects the current method
30 of identification and accountability and differentiation will be greatly reduced.

By replacing the need to rely solely on human visual detection and counting ability to differentiate the individual sponges from one another and account for their presence or lack thereof with a system as presented here, the medical community will be empowered with the ability to identify and account for individual surgical sponges in a vastly superior way.

5 In accordance with the present invention, each surgical sponge is made individually unique for a given surgical procedure and preferably from every other surgical sponge by assigning unique machine-readable information to each individual surgical sponge. The sponges therefore become distinguishable from each other in an automated manner providing for a more accurate and efficient system of identification and accountability of these medical items. The inventory of unique surgical
10 sponges created by the automated system before a surgical procedure via a scanning device which reads the machine-readable information off the sponges and inputs that information into a computer system can be compared to an inventory created either during or after the same procedure and an instant comparison of inventories be made to determine the presence, or lack thereof, of all the individual sponges.

15 Through the use of the herein described system, medical personnel will be able to not only determine if a sponge or sponges are missing faster and more reliably, but exactly which sponge or sponges are missing. This process may lessen the need for needlessly exposing a patient to x-ray radiation and further trauma by needless closing and reopening of an incision. This system will have the potential to vastly reduce the occurrence of retained surgical sponges. Furthermore, the
20 automatically created inventories of surgical sponges can be logged, becoming a permanent addition to a patient's medical file, and referenced at a later time for such needs as legal or medical reference. This herein described system will empower the medical community with the ability to raise the overall standard of health care while potentially saving costs for all parties involved from the patient, medical personnel, hospitals and insurance companies.

25 Other objects, advantages, and novel features will become apparent from the following detailed description of the invention when considered in conjunction with the accompanying drawings.

Brief Description of the Drawings

Figure 1 illustrates a preferred embodiment of the surgical sponge system of the present
30 invention.

Figure 2 is a side perspective view of a sponge incorporating the features of the present invention.

Figure 3 illustrates the use of a scanner for reading the data on the surgical sponges.

The same reference characters designate the same parts or elements throughout the
5 drawings.

Detailed Description of the Preferred Embodiments

Referring now to the drawings and the characters of reference marked thereon, Figure 1 illustrates the preferred embodiment of the surgical sponge system of the present invention, the
10 sponges being designated generally by numeral designations 10, 10', ... 10^N. Each sponge 10 includes a substrate 12 having unique machine-readable information 14 located thereon. This sponge material 16 may be conventional surgical sponge material, typically, folded woven cotton.

The substrate 12 is formed of inert, sterilizable material, which is capable of maintaining the machine-readable information 14. It may be, for example, cotton, polyester or a blend thereof. These
15 materials do not inhibit the basic function of the sponge 16. Various label designers and manufacturers which may fabricate suitable labels for use as substrates 12 may include Computype Inc., St. Paul, Minnesota; Information Plus Corp., Texas; and Polymark, Inc., Cincinnati, Ohio.

Referring now to Figure 2, it can be seen that the lower surface of the substrate 12 includes a layer of adhesive material 18 for attaching the substrate 12 to the sponge material 16. The adhesive material 18 is preferably of the type that provides attachment by application of heat thereto. The above-mentioned label manufacturers typically use such adhesive materials. However, the present invention preferably involves the addition of an x-ray detectable element in the adhesive material 18. Such an x-ray detectable element may include barium sulfate.

It is understood that although the x-ray detectable element has been described as being
25 contained within the adhesive material 18, it may alternately be included on the sponge material 16.

The machine-readable information 14 on each sponge is unique for at least one surgical procedure. The machine-readable information 14 is preferably presented in bar code form. It may be presented by commercially available inkjet technology or thermal transfer processes. Examples of

companies providing these capabilities include, for example, Computype, Inc.; Zebra, Inc., Vernon Hills, Illinois; and Information Plus Corporation.

Although the machine-readable information 14 is unique for at least one surgical procedure, it is preferably absolutely unique; i.e. no two sponges will contain the same information, even in different
5 surgical procedures.

The machine-readable information 14 may be present in either one, two or three-dimensional technologies in one of various commercially viable forms.

A sponge may include unique human-readable information thereon associated with its respective unique machine-readable information. This human-readable information is provided as a
10 backup method if there is a machine failure in reading the information in its machine-readable form.

Referring now to Figure 3, sponges 10, 10', ... 10^N, are shown being scanned by a data reading device 20. The data reading device 20 is connected to a computer (not shown). The data reading device 20 may be, for example, a bar code scanner. Before each surgical procedure, an inventory is created of the surgical sponges to be used for that particular procedure. To account for
15 and identify the surgical sponges either during or after this surgical procedure another inventory can be created by scanning the sponges to check and see if they are all accounted for. The missing sponge(s) can be identified.

Obviously, many modifications and variations of the present invention are possible in light of the above teachings. It is, therefore, to be understood that within the scope of the appended claims,
20 the invention may be practiced otherwise than as specifically described.

What is claimed and desired to be secured by Letters Patent of the United States is: